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EXAMINER				
LANDAU, SHARMILA GOLLAMUDI				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/825,992

Applicant(s)

TUTUNCU ET AL.

Examiner

Sharmila Gollamudi Landau

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 8, 10, 11, 13-21, 23, 24 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 10, 11, 13-21, 23, 24 and 28-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/3508)
Paper No(s)/Mail Date 5/5/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of Request for Reconsideration, IDS, and Rule 132 Affidavits filed 5/5/08 is acknowledged. Claims **1-5, 7-8, 10-11, 13-21, 23-24, and 28-32** are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7-8, 10-11, 13-14, 17, 20, 23-24, 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,284,659 to Cherukuri et al in view of WO 99/579427 to Le et al.

Cherukuri et al disclose encapsulated flavor with bioadhesive properties. The compressed confectionary provides controlled release of the flavor and a unique mouthfeel by using bioadhesives. The compressed tablet is characterized by discrete phases contained within. See Figure 5 and 6 wherein both phases 1 and 2 have a surface on the exterior of the product.

The compressed tablet include: (a) a first flavor ingredient present in an amount from about 0.1% to 0.5% by weight of a hydrophilic composition with which it is intimately bound to provide instantaneous delivery of the active ingredient or flavor; and (b) a second flavor ingredient present in an amount of from about 3% to 30% by weight of a hydrophobic encapsulating composition containing a bioadhesive so as to provide delivery of the second flavor ingredient over a extended period of time while both the tablet and encapsulated flavors adhere to the moist areas of the oral cavity.

The confectionary compressed tablet is made of a sugar or sugarless base. See column 8, lines 66-67 and column 10, lines 40-45. Sugars taught include sucrose, glucose, dextrose, fructose, and sugar alcohols include sorbitol, mannitol, and xylitol. See column 9, lines 7-21. Emulsifiers (surfactants) are taught in an amount of 2-7%. See column 8, lines 40-55.

Cherukuri also teaches that in addition to encapsulated flavor ingredients, a bio-effecting agent such as breath fresheners, breath deodorants, *antigingivitis agents*, and combinations thereof may also be used. See column 7, lines 30-45.

Table II, example III discloses a product wherein the shell component contains 97.676% sugar, 0.748 % of a breath deodorant (copper gluconate), 0.234% lubricant, 1.280% flavor beads, 0.062% liquid flavor. This shell region reads on instant “salivation region” since this region contains the bio-effecting agent (the breath freshener). The core comprises 40.32% fat encapsulation material of Table I and 59.68% of a diluent. Table I discloses a fat encapsulation containing 48% partially hydrogenated soybean oil, 5% glycerol monostearate, 10% vegetable oil, 2% flavor oil, and 20% bioadhesive. This core region read on instant “oral comfort region” since this phase predominantly comprises lipids. Cherukuri teaches the diluent may be selected

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from lactose (sugar), microcrystalline cellulose, starch, talc, sorbitol, mannitol, xylitol, maltitol, xylitol, other sugar alcohols or sugars. See column 8, lines 60-65. Note that this diluent reads on applicant's confectionary base of the oral comfort region. The tablet is made by mixing each respective composition with the respective components separately and then the core is compressed into the shell portion. See column 10, line 40 to column 11, line 28.

Although Cherukuri teaches the use of bioeffecting agents in the shell portion, Cherukuri does not teach the specific use of an acidulent in the shell portion.

Le teaches co-processed comestible, confectioneries, pharmaceuticals, and dentifrices comprising an acid and water-soluble crystalline compounds. Le teaches that the prior art conventionally uses acidulents in comestible for a variety of reasons. For instance, acidulents may be used to increase saliva production for the treatment of xerostomia and dry mouth; the use of acids to soften plaque on teeth; as flavor enhancers to improve the release of flavor in confectionary products such as hard candies. See page 1. Le teaches the acidulent may be inorganic or organic acids including phosphoric acid, citric acid, malic acid, succinic acid, fumaric acid, ascorbic acid, etc. see page 5, lines 13-25. The acidulent is utilized in an amount of 0.2% of the entire composition (note example 4 in combination with Table 2 formulation wherein the acidulent is 5.5% of the coprocessed formulation and the coprocessed formulation is 3.75% of the composition)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Cherukuri et al and Le et al and utilize an acidulent as the bio-effecting agent in the shell portion of Cherukuri's composition. Firstly, one would have been motivated to do so with a reasonable expectation of success since Cherukuri teaches the use of

bio-effecting composition in the composition; thus a skilled artisan would have been motivated to utilize an acidulent in Cherukuri's example as the bio-effecting agent in place of the breath freshener if one desired to treat xerostomia and dry mouth or reduce plaque on the teeth. A skilled artisan would have reasonably expected success since Cherukuri teaches various bio-effecting agents may be used including antigingivitis agents and Le teaches the acids reduce plaque, i.e. having an antigingivitis activity. Secondly, one would have been motivated to utilize an acidulent in the shell portion since Cherukuri teaches the shell portion provides the release of the first flavor (the rapid release portion) and thus a skilled artisan would have been motivated to utilize an acidulent in the shell portion since Le teaches acidulents are conventionally utilized to improve and enhance the release of the flavor. Therefore, a skilled artisan would have been motivated to utilize an acidulent in the shell portion to increase the rate of release of first flavor in the hydrophilic portion (shell portion).

With regard to claim 14, the manipulation of the concentration of emulsifier in the core composition of example III is considered to be obvious to one of ordinary skill. The examples utilize a range of 5%; however one would have been motivated to utilize the instant range of 0.5-4% since Cherukuri teaches the emulsifier may be utilized in a range of 2-7%. Therefore, the range taught by Cherukuri overlaps the instant range.

Response to Arguments and Rule 132 Declaration

Applicant argues that there is no reason for a skilled artisan to look to Le to reduce plaque. Applicant argues that acids only reduce plaque in combination with an abrasive. Applicant argues that edible acids do not have any effect on plaque or any antigingivitis activity. Therefore, there is not reason to combine Cherukuri and Le. In the Rule 132 Declaration Dr.

Stephen Moss states that Le describes a method of removing plaque but only using a combination of an acid and abrasive. The Rule 132 states that neither Le nor Muhler disclose the use of acid as an anti-gingivitis agent and in Dr' Moss's experience, acids are not nor used as anti-gingivitis agents. Dr. Moss states "I do not believe that acid by itself would remove plaque from teeth or act as an antingivitis agent, I do not believe that a desire to reduce plaque on teeth would have been a valid reason to combine an acid according to Le in a tablet according to Cherukuri."

Applicant's arguments filed 5/5/08 have been fully considered but they are not persuasive. The Rule 132 Declaration of Dr. Moss filed 5/5/08 is insufficient to overcome the rejections.

First, it is noted that the Rule 132 Declaration is an opinion Declaration and has been given little weight since it does not provided any factual evidence. Second, the above rejection contained several advantages of using acidulents other than the function of reducing plaque. Le teaches acidulents are commonly used in edible and dentifrice products for a variety of reasons including (1) increasing saliva production to treat xerostomia or dry mouth; (2) for use in exercising; (3) to soften plaque; and (4) as flavor enhancers and to improve the release of flavors in confectionary products. Further, Cherukuri suggests the use of antingivitis agent and Le teaches acids "soften plaque". It is noted that the instant claims do not exclude combinations of active agents and thus the claims do not exclude Le's use of an acidulent and abrasive to treat plaque and thereby preventing or treating gingivitis.

Assuming that softening plaque does not help treat gingivitis and does not act as an antingivitis agents, there are other reasons for using acidulents. For instance, Cherukuri teaches

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the shell portion, which reads on the salivation region, releases the active agent or flavor instantaneously. Le teaches acidulents are known to improve the release of flavors. Thus, a skilled artisan would have been motivated to utilize an acidulent in the shell portion increase the rate of release of first flavor in the hydrophilic portion (shell portion). Additionally, Cherukuri teaches the use of bio-effecting active to release in the oral cavity and Le teaches acidulents are used to treat xerostomia. Thus, if a skill artisan wanted to treat xerostomia, one would have substituted Cherukuri's breath freshener in the example with an acidulent. Applicant has not addressed the other reasons relied upon to combine Cherukuri and Le.

The Rule 132 Declaration of Donald Mayer provides the consumer call data in connection with AQUADROPS. Applicant argues that these calls demonstrate the unexpected functional effect of the claimed hard candy.

The Rule 132 Declaration of Mr. Mayer filed 5/5/08 is insufficient to overcome the rejections for the following reasons. It is first noted that the Declaration refers to AQUADROPS, however the exact composition of this product is not given. Thus, it is not possible to make a conclusion of unexpectedness and ascertain if the claims are commensurate in scope without the specifics of the composition. Second, it is noted that the responses state that the product helped with dry mouth; however this is expected in light of Le's teachings. Le discloses that it is known in the art to utilize acidulents to treat dry mouth and xerostomia.

Therefore, for the above reasons, the rejection is maintained.

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,284,659 to Cherukuri et al in view of WO 99/59427 to Le et al in further view of Aldrich (4,517,205).

The disclosure of Cherukuri and Le have been set forth above.

The reference do not teach the instant method of making the confectionary product.

Aldrich teaches a method of co-depositing two component hard candy in a mold cavity that produces two distinct areas. See column 2, lines 15-30 and Figures. The method provides an efficient method that is readily adaptable to commercial production of candies with two components. See column 2, lines 5-15.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references and simultaneously deposit the two distinct regions in a mold cavity. One would have been motivated to do so since Aldrich teaches this it is an efficient method that is easily adaptable for commercial production of candies comprising two-components such as a shell portion and core portion.

Response to Arguments

Applicant has not argued the merits of the instant rejection specifically. Thus, the rejection is maintained for the reasons of record.

Claims 15-16, 21, 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,284,659 to Cherukuri et al in view of WO 99/579427 to Le et al in further view of Hughes (6,004,538).

The disclosure of Cherukuri and Le have been set forth above.

The combination of references is lacking the use of an acidulent and the cooling compound specifically.

Hughes teaches an oral composition in various forms including candies. Hughes teaches dental hygiene preparations typically contain antiplaque and/or antitartar agents, as well as

antimicrobial agents and flavorants. Hughes teaches antimicrobial action could affect plaque formation by either reducing the number of bacteria in the mouth/dentures or by killing those bacteria trapped in the film to prevent further growth and metabolism. Flavorants may alleviate the problem of bad breath via a deodorizing action. Hughes teaches some antimicrobial agents, such as menthol, also serve as breath deodorizers.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and utilize menthol as the flavorant taught in Cherukuri's shell. One would have been motivated to do so since Hughes teaches menthol not only serves as a flavorant but it reduces plaque on the teeth due to its antimicrobial action and it reduces bad breath. Therefore, a skilled artisan would have been motivated to specifically utilize menthol as the flavorant in the shell portion for its various advantageous functions. Moreover, one would have specifically utilizes menthol in the shell area specifically since the shell area comprises the bioeffecting agents. Further, Le teaches the use of acids to soften plaque on the teeth and thus a skilled artisan would have been motivated to additionally utilize menthol for its additive effect.

Response to Arguments

Applicant has not argued the merits of the instant rejection specifically. Thus, the rejection is maintained for the reasons of record.

Claims 1-5, 7-8, 13-18, 23, 29, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bealin-Kelly (6,306,429) in view of WO 97/06695.

Bealin-Kelly teaches a confectionary composition comprising cooling and warming regions, which are in distinct and discrete regions. Bealin-Kelly teaches that various

configurations may be utilized including a centre-filled drop that provides a sequential release of the compositions or a configuration that provides differential release profiles as described in WO97/06695, which is incorporated by reference. See column 2, lines 10-25.

Bealin-Kelly teaches sugar base for a hard candy shell comprises from about 30% to about 85% glucose syrup and from about 15% to about 70% sucrose. Alternatively, a sugar-free base maybe used for the shell including bulk sweeteners such as isomalt, maltitol and sorbitol. Isomalt and maltitol are preferred. See column 6, lines 1-15. The “filling” is made of 50-75% of bulk sweetener and may be made of sugar free composition such as sorbitols. See column 5, lines 40-45. Phospholipids such as lecithin are used in an amount of 0.001-1%. See column 5, lines 20-25.

Example 1 teaches a composition comprising a candy containing 49.37% sucrose, 49.37% glucose syrup, 0.27% lemon oil, 0.08% menthol (cooling compound), and 0.91% citric acid (acidulent). The filling contains 84.3% high fructose corn syrup, 15% glycerin, 0.02% lecithin (surfactant), 0.314% lemon oil, and 0.16% color. See example 1. Note that the shell reads on the instant salivation region and the fill reads on the oral comfort region. The regions are mixed separately and co-extruded.

Bealin-Kelly does not exemplify the instant configuration.

WO 97/06695 teaches a confectionary product comprising a coolant composition and flavoring composition in separate and distinct regions. The composition may take various form including hard candies wherein the distinct regions are in separate layers. See page 3. WO ‘695 teaches using molds in which the respective composition is placed and each composition has a surface on the exterior of the product. See examples.

It would have been obvious to one of ordinary skill in the art at the time the invention was made Bealin-Kelly and WO '695 and utilize a configuration wherein the respective compositions are in separate layers rather than a "centre-filled drop". One would have been motivated to do so with a reasonable expectation of success since Bealin-Kelly incorporates the teachings of WO '695 and suggests various configurations may be used including the configuration taught in WO '695, i.e. distinct regions.

Response to Arguments

Applicant argues that Bealin-Kelly teaches a liquid center fill and not a hard candy. Applicant argues that the lipid, i.e. lecithin, is only used in the liquid fill. Thus, applicant argues, "the Examiner has not identified a lipid or surfactant oral comfort ingredient arranged with a surface on the exterior of the product, as claimed, and thus these rejections should be withdrawn."

Applicant's arguments filed 5/5/08 have been fully considered but they are not persuasive. It appears applicant is arguing that if the fill is liquid, it cannot be configured with both regions having an exterior region. First, it is noted that Bealin-Kelly teaches lecithin is used in the "liquid" fill. However, applicant's attention is directed to column 4, lines 55-58 in which Bealin-Kelly teaches, "The filling can be a solid, particularly a powder, or a liquid, including forms of intermediate consistency such as a paste or a gel." Therefore, the term "liquid" includes viscous consistency. Thus, the instant configuration is merely a design choice and clearly Bealin-Kelly suggests other configurations including those taught in WO 97/06695. WO '695 teaches confectionary products have distinct and discrete regions wherein both regions can be a surface on the exterior of the product. If applicant is asserting that the paste or gel cannot be designed in

the claimed configuration due to its consistency, applicant's attention is directed to Aldrich (US 4,517,205), prior art of record. Aldrich demonstrates it is possible to configure a hard portion and a viscous portion in the instant configuration, i.e. wherein both regions have an exterior surface.

The Rule 132 Declaration of Donald Mayer provides the consumer call data in connection with AQUADROPS. Applicant argues that these calls demonstrate the unexpected functional effect of the claimed hard candy.

The Rule 132 Declaration of Mr. Mayer filed 5/5/08 is insufficient to overcome the rejections for the following reasons. First, it is noted that Bealin-Kelly teaches an oral comfort region and a salivation region; thus the reference is not deficient in this sense. Therefore, results showing the unexpectedness of the acid and lipid/surfactant region is not persuasive since the prior art teaches the combination of both. Bealin-Kelly only lacks the instant configuration. It is the examiner's position that this an obvious design choice based on Bealin-Kelly's suggestion to utilize other configurations. Thus, the Rule 132 Declaration does not establish the unobviousness of the instant configuration to overcome the rejection based on obviousness.

Therefore, the rejection is maintained for the above reasons.

Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bealin-Kelly (6,306,429) in view of WO 97/06695 in further view of National Institute of Dental and Craniofacial Research, NIH publication, June 1999.

The disclosure of Bealin-Kelly and WO '695 have been set forth above.

Although Bealin-Kelly teaches the use of the confectionary product for providing soothing properties, Bealin-Kelly does not specifically teach the use of the product to treat xerostomia.

The NIH publication teaches xerostomia (dry mouth) is caused by several factors such as the side effects of medication, diseases, chemotherapy, etc. The symptoms include sticky, dry mouth, trouble chewing, swallowing, tasting, a burning feeling in the mouth, a dry feeling in the throat, cracked lips, a dry tongue, and mouth sores. The publication teaches methods of treating xerostomia include, chewing sugarless gum or sucking on sugarless gum to stimulate saliva flow. Candies that have citrus, cinnamon, or mint are good choices.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and Bealin-Kelly's composition to treat xerostomia. One would have been motivated to do so since Bealin-Kelly teaches a sugarless confectionary product containing citrus flavors and menthol and the NIH publication teaches sucking on sugarless candies, particularly ones that contains citrus and mint, treat xerostomia. Furthermore, a skilled artisan would have expected success since Bealin-Kelly teaches the confectionary provide soothing properties and the symptoms of dry mouth include a burning feeling in the mouth and dry feeling in the mouth, and mouth sores.

Response to Arguments

Applicant has not argued the merits of the instant rejection specifically. Thus, the rejection is maintained for the reasons of record.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bealin-Kelly (6,306,429) in view of WO 97/06695 in further view of US patent 6,099,880 to Klacik et al.

The disclosure of Bealin-Kelly and WO '695 have been set forth above.

The reference does not teach a mold having a ridge to separate the components.

Klacik et al discloses a patterned candy containing agents such as sugar, sugar alcohol, coconut oil, and flavors. Klacik et al teach the mold having separate region and depositing mixtures in each segment to form a product with visually distinct regions. Klacik teaches this method is a simple method of forming distinct regions. See column 1, lines 30-50.

It is would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references and utilize a mold with a ridge. One would have been motivated to do so since Klacik et al teach an economical and simple process of producing a product having distinct regions using a mold having a ridge. Therefore, it is obvious to utilize a ridge to further maintain the separation and distinction of each respective region.

Response to Arguments

Applicant has not argued the merits of the instant rejection specifically. Thus, the rejection is maintained for the reasons of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is (571) 272-0614. The examiner can normally be reached on Monday- Friday (8:30-6).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharmila Gollamudi Landau/
Primary Examiner, Art Unit 1611